

CLAIMS

We claim:

- 1) A pharmaceutical composition comprising:
 - a) a COX-II inhibitor;
 - b) a muscle relaxant; and
 - c) at least one pharmaceutical excipient.
- 5 2) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor binds COX-II receptors selectively over COX-I receptors.
- 3) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor binds 10 COX-II receptors specifically.
- 10 4) The pharmaceutical composition of claim 1, wherein the weight ratio of COX-II inhibitor to muscle relaxant varies from (12.5:2.2) to (50:8).
- 5) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor is selected 15 from the group consisting of central muscle relaxants and neuromuscular blocking agents.
- 15 6) The pharmaceutical composition of claim 1, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbents, alkalizing agent, antioxidants, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet 20 direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.
- 20 7) The pharmaceutical composition of claim 1, wherein the muscle relaxant is selected 25 from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol (SOMA®), chlorphenesin, chlorphenesin carbamate, chlorzoxazone (PARAFON FORTE®), chlormezanone, cyclobenzaprine (FLEXERIL®), dantrolene, decamethonium, diazepam, dyphylline, eperisone, ethaverine, gallamine triethiodide, hexafluorenium, mephenesin, metaxalone (SKELAXIN®), methocarbamol (ROBAXIN®), metocurine iodide, orphenadrine (NORFLEX®), pancuronium, 30 papaverine, pipecuronium, pridinol (pridinolum), succinylcholine, theophylline,

tizanidine, tolperisone, tubocurarine, vecuronium, idrocilamide, ligustilide, cnidilide, and senkyunolide.

8) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor is selected from the group consisting of rofecoxib (VIOXX™, MK-0966), celecoxib (CELEBREX™, SC-58635), flosulide (CGP-28238), NS-398, DUP-697, meloxicam, 6-methoxy-2-naphthylacetic acid (6-MNA), nabumetone (prodrug for 6-MNA), etodolac, nimesulide, SC-5766, SC-58215, T-614, combinations thereof.

5 9) A method of treating pain in a mammal comprising the step of administering a pharmaceutical composition according to any one of claims 1-8, wherein the pharmaceutical composition provides therapeutically effective levels of each drug when administered to a mammal.

10 10) A pharmaceutical dosage form comprising:

15 a) a therapeutically effective amount of a COX-II inhibitor;

b) a therapeutically effective amount of a muscle relaxant; and

c) at least one pharmaceutical excipient.

11) The pharmaceutical dosage form of claim 10, wherein the dosage form is selected from the group consisting of a gel, cream, ointment, pill, tablet, capsule, liquid, suspension, osmotic device, bead, granule, spheroid, particulate, paste, prill, reconstitutable solid, powder, and injectible liquid.

20 12) The pharmaceutical dosage form of claim 10, wherein the dosage form independently provides a controlled, delayed, sustained, immediate, timed, slow or rapid release of each of the COX-II inhibitor and the muscle relaxant.

13) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutically effective plasma levels of the COX-II inhibitor for a period up to at

25 least about 12 hours after administration.

14) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutically effective plasma levels of the muscle relaxant for a period of time after administration sufficient to enhance the therapeutic benefit provided by the COX-II inhibitor.

15) The pharmaceutical dosage form of claim 10, wherein the pharmaceutical dosage form is adapted for oral, buccal, ocular, otic, gastrointestinal, dermal, rectal, vaginal, cervical, intrauterine, epidermal, transdermal, implant, mucosal, parenteral, sublingual, nasal, or pulmonary delivery.

5 16) The pharmaceutical dosage form of claim 10, wherein the muscle relaxant is selected from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol (SOMA®), chlorphenesin, chlorphenesin carbamate, chlorzoxazone (PARAFON FORTE®), chlormezanone, cyclobenzaprine (FLEXERIL®), dantrolene, decamethonium, diazepam, dyphylline, eperisone, ethaverine, gallamine triethiodide, 10 hexafluorenium, mephenesin, metaxalone (SKELAXIN®), methocarbamol (ROBAXIN®), metocurine iodide, orphenadrine (NORFLEX®), pancuronium, papaverine, pipecuronium, pridinol (pridinolum), succinylcholine, theophylline, tizanidine, tolperisone, tubocurarine, vecuronium, idrocilamide, ligustilide, cnidilide, and senkyunolide.

15 17) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor is selected from the group consisting of rofecoxib (VIOXX™, MK-0966), celecoxib (CELEBREX™, SC-58635), flosulide (CGP-28238), NS-398, DUP-697, meloxicam, 6-methoxy-2-naphthylacetic acid (6-MNA), nabumetone (prodrug for 6-MNA), etodolac, nimesulide, SC-5766, SC-58215, T-614, combinations thereof.

20 18) The pharmaceutical dosage form of claim 10, wherein each drug is released rapidly and the dosage form provides therapeutically effective levels of each drug for a period of at least 12 hours.

19) The pharmaceutical dosage form of claim 18, wherein the period is about 12 to 60 hours.

25 20) The pharmaceutical dosage form of claim 19, wherein the period is about 12 to 30 hours.

21) The pharmaceutical dosage form of claim 19, wherein the period is about 18 to 48 hours.

22) The pharmaceutical dosage form of claim 10, wherein the plasma level of one drug is 30 dependent upon the plasma level of the other drug.

23) The pharmaceutical dosage form of claim 10, wherein the plasma level of one drug is independent of the plasma level of the other drug.

24) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutic plasma levels for the muscle relaxant in an amount sufficient to provide a therapeutic benefit to a subject to whom it is administered.

5 25) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutic plasma levels for the COX-II inhibitor generally in the range of about 90 ng to about 300 ng per ml of plasma.

10 26) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released sequentially.

27) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released concurrently.

28) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released in spaced apart periods of time.

15 29) The pharmaceutical dosage form of claim 10, wherein each drug is independently released according to a rapid, immediate, controlled, sustained, slow, timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

30) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the COX-II inhibitor and a controlled release of the muscle relaxant.

20 31) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the COX-II inhibitor and a rapid release of the muscle relaxant.

32) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the muscle relaxant and a rapid release of the COX-II inhibitor.

25 33) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the COX-II inhibitor and of the muscle relaxant.

34) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the muscle relaxant and a delayed but rapid release of the COX-II inhibitor.

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35) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the muscle relaxant and a timed but controlled release of the COX-II inhibitor.

5 36) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the COX-II inhibitor and a delayed but rapid release of the muscle relaxant.

37) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the COX-II inhibitor and a timed but controlled release of the muscle relaxant.

10 38) The pharmaceutical dosage form of claim 10, wherein the weight ratio of COX-II inhibitor to muscle relaxant varies from 12.5:2.2 to 50:8.

39) A method of treating pain in a mammal comprising the step of administering a dosage form according to any one of claims 10-38, wherein the dosage form provides therapeutically effective levels of each drug when administered to a mammal.

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